

Appl. No. 10/036,418  
Atty. Docket No. 9056#LS  
Amdt. Dated 20 October 2004  
Reply to Office Action of 20 October 2004  
Customer No. 27752

### REMARKS

Claims 1-46 are pending in the present application. Herein, Applicants present no amendments, add no new claims, and cancel no claims. No additional claims fee is believed to be due.

Applicants also want to draw attention to the change in Attorney Docket No. from 005126.00009 to 9056#LS.

Applicants also wish to draw attention to the correspondence that was filed to notify a CHANGE OF CORRESPONDENCE ADDRESS and addition of ASSOCIATE POWER OF ATTORNEY on 14 November 2002, a copy of which is attached herewith.

### Response to Requirement for Restriction of Inventions

The Examiner has required, under 35 USC §121, election of a single disclosed invention for prosecution on the merits. Pursuant to this requirement, Applicants hereby elect to prosecute the invention of Group III, namely, Claims 24-37, drawn to a method for assaying INGAP, classified in class 435, subclass 7.8. This election is made with traverse under 37 CFR §1.143.

### Traversal of Restriction Requirement

The traversal of the indicated restriction requirement is made as Applicants believe it is improperly made. Applicants submit that the Office Action does not show the inventions defined by the groups are independent and distinct. Applicants address each issue raised by the Office Action below.

In Paragraph 2, the Office Action states that inventions II, IV and I, III are related as product and process of use. The Office Action further states, citing MPEP §806.05(h), that the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using the product. The Office Action alleges that the products recited in group II or IV, i.e. antibodies, can be used in a materially different process of using, such as purification or isolation. Applicants respectfully disagree.

Antibodies are proteins that recognize and bind their respective antigenic determinants. An antibody may be used in an assay method to detect or quantitate the antigen (as in an ELISA

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or a Western blot), or it may be used in a purification of the antigen (as in an antibody affinity column). It may also be used in a method of treatment of a disease (as in an antibody therapy such as Herceptin (RTM)). In the corresponding subsequent steps of the uses described above, the use of a labeled anti-antibody would allow the detection or quantitation of the antigen; elution using a higher salt concentration would allow the purification of the antigen; and complement activation followed by phagocytosis in a patient body would allow the clearance of tumor cells bearing the antigen. However, in all of these "uses", the underlying property that is necessary and responsible for successfully achieving the "use" is the same, i.e. the antibody binding to its complementary antigenic determinant on the antigen. Applicants submit that use of the antibody for purification or isolation does not constitute a "materially different" use from use of the antibody in a method for assaying INGAP. Therefore, Applicants submit that the inventions of the groups I and II, and groups III and IV should be examined together.

In Paragraph 3, the Office Action alleges that inventions I and III are unrelated. Citing MPEP §806.04, and MPEP §808.01, the Office Action states that the inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. It further alleges that in the instant case the different inventions possess patentably distinct features, e.g., the feature of "SEQ ID NO: 1" in invention I is not required by the claims of invention III.

In Paragraph 4, the Office Action alleges that inventions II and IV are unrelated. Citing MPEP §806.04, and MPEP §808.01, the Office Action states that the inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. It further alleges that in the instant case the different inventions possess patentably distinct features, e.g., the feature of "SEQ ID NO: 1" in invention II is not required by the claims of invention IV. Applicants respectfully disagree and provide a common analysis for points 3 and 4 of the Office Action.

Claim 1 (exemplifying group I) and claim 24 (exemplifying group III), both are for assaying the INGAP protein. The method of claim 1 utilizes an antibody that is raised against SEQ ID NO: 1, while the method of claim 24 utilizes an antibody that is raised against one of the SEQ ID NOs: 2, 3, or 4. Any antibody raised against any antigenic determinant of the INGAP protein would bind and therefore could be used to assay the INGAP protein. Therefore, the methods of claims 1-14 (group I), or methods of claims 24-37 (group III), would all be useful for assaying INGAP molecules, sharing a common function. Thus, Applicants submit that inventions I and III are related and should be examined together.

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SEQ ID NOs: 1, 2, 3, and 4 are all fragments of a single protein molecule, the Islet Neogenesis Associated Protein (INGAP) molecule. As a result, the antibodies generated using SEQ ID NOs: 1, 2, 3, or 4 (inventions II and IV), would recognize and bind the full-length INGAP protein. It is known in the art that a full-length protein may be injected in an animal and the resulting polyclonal antibodies would recognize various antigenic epitopes of that protein. Here, the Applicants have raised antibodies to different regions of the INGAP protein in order to generate more reagents that may be selectively used in various assay methods. However, all the antibodies share the same property, namely, ability to bind INGAP protein. Thus, each of the invention shares common functions, modes, and effects with the other inventions. Therefore, Applicants submit that claims under inventions I, II, III, and IV should be examined together.

Based on the analysis and arguments presented above for points 2, 3, and 4, Applicants submit that inventions I, II, III, and IV, drawn to claims 1-46 should be searched and examined together, and the restriction requirement should be withdrawn.

Ms. Kagan of the law firm Banner & Witcoff had advised us of the telephone call of 9/15/2004. Applicants thank the Examiner and confirm that The Procter & Gamble Company will be prosecuting this application.


#### Conclusion

Applicants have made an earnest effort to place their application in proper form for examination and allowance. In view of the foregoing, Applicants respectfully request withdrawal of the restriction requirement, reconsideration of this application, and allowance of Claims 1-46.

Respectfully Submitted,

THE PROCTER & GAMBLE COMPANY

By

  
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Date: 20 October 2004  
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